JUL 2 4 2002

COMPLEWARE® CORPORATION

K020804

510(k) SUMMARY
of
SAFETY and EFFECTIVENESS

A. General Information

1.	*Submitter's Name:*	CompleWare Corporation
2.	*Address:*	221 East Burlington Street Iowa City Iowa 52240
3.	*Telephone:*	319-338-8888
4.	*Contact Person:*	Kay Weiler
5.	*Date Prepared:*	December 18, 2001
6.	*Registration Number:*	FDA Form 2891 Submitted

B. Device

1.	*Name:*	ClinDataLink Version 1.0 for Spirometry
2.	*Trade Name:*	ClinDataLink
3.	*Common Name:*	Application Software and Diagnostic Spirometry
4.	*Classification Name:*	Spirometer, Diagnostic
5.	*Product Code:*	BZG
6.	*Class:*	II
7.	*Regulation Number:*	868.1840

C. Identification of Legally Marketed Devices

1.	*Name:*	SpiroCard
2.	*K Number:*	K973138

3. *Date Cleared:* October 28, 1998

D. Description of the Device

ClinDataLink Version 1.0 is a software application that will be used to collect spirometry data for clinical research studies using QRS Diagnostics, LLC Type II PCMCIA cards and software development kit.

ClinDataLink will capture demographic data, spirometry data (FVC, SVC, and MVV) and time/date of visits based upon Protocol Wizard.

The components of the ClinDataLink System are the following:

- ClinDataLink Version 1.0 on CD-ROM.
- ClinDataLink User's Guide
- ClinDataLink Help File
- Pentium II with a 200 MHZ processor with 32 MB of RAM and 2 GB hard drive
- Windows 98, 98SE, ME, or 2000 Operating System
- QRS PCMCIA Card Type II
- QRS Software
- QRS SpiroCard, PC Card to sample the respiratory function of a patient via an attached pressure/transducer/mouthpiece and convert the measured pressure difference to an electrical signal.
- QRS Pressure Tubes
- QRS Disposable Pneumotach (Mouthpiece)
- QRS User's Manual

E. Intended Use Statement

The ClinDataLink Version 1.0 is an application software that will be used to collect spirometry data for clinical research studies using the FDA Cleared QRS

The ClinDataLink Version 1.0 is an application software that will be used to collect spirometry data for clinical research studies using the FDA Cleared QRS Diagnostics, LLC Type II PCMCIA cards and software development kit. The QRS SpiroCard was cleared by the agency on October 28, 1998 via K973138.

ClinDataLink will permit the entry and management of these data and the transmission to a central or local database for integration with other clinical research data.

ClinDataLink is compliant with 21 CFR Part 11 requirements for electronic records.

F. Technical Characteristics Summary

The ClinDataLink Version 1.0 for Spirometry is substantially equivalent to the QRS SpiroCard cleared on October 28, 1998.

The ClinDataLink utilizes the QRS SpiroCard to collect spirometry data for clinical research studies.

The ClinDataLink was verified by QRS to support the usage of four operating systems with their components.

CompleWare Corporation undertook extensive validations of the four operating systems via standard verification/validation activities.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 4 2002

Ms. Kay Weiler
Vice President
CompleWare Corporation
221 East Burlington Street
Iowa City, Iowa 52240

Re: K020004
Trade/Device Name: ClinDataLink Version 1.0 for Spirometry
Regulation Number: 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: April 24, 2002
Received: April 25, 2002

Dear Ms. Weiler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: *To be determined*

Device Name: ClinDataLink™ Version 1.0 for Spirometry

Indications for Use:

- The ClinDataLink™ Version 1.0 for Spirometry is an application software that will collect spirometry data for clinical research studies in male/females, pediatrics to adults, and measure FVC, MVV, and SVC, in a hospital, clinic, or home use environment.
- Prescription device by a physician.

PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR OVER-THE-COUNTER USE ____
(optional Form 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020004